IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

MORTON GROVE PHARMACEUTICALS, INC.,	)	
Plaintiff,	)	No. 08-CV-1384
vs.	)	Judge Bucklo Magistrate Judge Mason
THE NATIONAL PEDICULOSIS ASSOCIATION, INC.,	)	**JURY TRIAL DEMANDED**
Defendant.	)	

THE NATIONAL PEDICULOSIS ASSOCIATION, INC.'S OPPOSITION TO PLAINTIFF'S MOTION TO STRIKE ALLEGATIONS AND DEFENSES IN DEFENDANT'S ANSWER AND COUNTERCLAIM

INDEX OF EXHIBITS

EXHIBIT 1

FDA Talk Paper

T03-19
March 28, 2003

Media Inquiries: 301-827-6242
Consumer Inquiries: 888-INFO-FDA

FDA Issues Health Advisory Regarding Labeling Changes for Lindane Products

The Food and Drug Administration (FDA) today issued a Public Health Advisory concerning the use of topical formulations of Lindane Lotion and Lindane Shampoo for the treatment of scabies and lice. The advisory announces significant updates to the labeling of these products. These labeling changes include additional warnings and the addition of a Medication Guide to be distributed directly to patients.

Labeling for Lindane products has been changed to include a boxed warning which highlights the most important safety issues associated with use of these products. The boxed warning contains information to better inform both healthcare professionals and patients regarding the potential risks associated with the use and misuse of Lindane.

The warning emphasizes that Lindane products have been, and continue to be, indicated as a second-line therapy for the treatment of scabies and lice. While FDA believes that the benefits of Lindane outweigh the risks when used as directed, given the potential for neurotoxicity, patients should only be treated with these medications if other treatments are not tolerable or other approved therapies have failed.

The new boxed warning also states that Lindane Lotion and Lindane Shampoo are to be used with caution in patients who weigh less that approximately 110 pounds (50 kilograms). These products are not recommended for use in infants, and are contraindicated in premature infants. These warnings are based on reports to the FDA's voluntary reporting system which described approximately one half of reported adverse events occurred in pediatric patients.

It is estimated that in the United States up to 1 million prescriptions are written each year to treat new cases of head lice and scabies, which occur mostly in school-age children. Since Lindane is absorbed through the skin, and because younger children have more skin surface area per pound of body weight than adults, the amount that is absorbed may result in higher blood levels of Lindane in children than that seen in adults. Animal studies have also shown that younger animals are more susceptible to the neurological side effects seen with Lindane use.

Because most of the serious adverse events reported with Lindane products are due to misuse and overuse, especially with the Lotion, product package sizes will be limited to 1 and 2 ounces. It is very important that patients understand the importance of using this medication in a manner consistent with the product labeling.

The instructions for use and information about adverse events will also be provided to patients in the form of a Medication Guide. By law, the Medication Guide must be dispensed by pharmacists directly to the patient with each new prescription of Lindane Lotion or Lindane Shampoo.

Other changes in the labeling address FDA concerns of potential increased risk of adverse reactions associated with the use of Lindane products in immuno-compromised patients, such as those with HIV infection, or patients on medications, such as antidepressants, that may increase the chances of having a seizure.

Given the possible risks associated with the use of Lindane, healthcare providers should consider

this new safety information when deciding whether to prescribe Lindane Lotion or Lindane Shampoo for patients who may be at risk for serious adverse drug events.

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Additional Information on Lindane

EXHIBIT 2

FDA Public Health Advisory: Safety of Topical Lindane Products for the Treatment of Scabies and Lice

The Food and Drug Administration (FDA) has issued a Public Health Advisory (PHA) concerning the use of topical formulations of Lindane Lotion and Lindane Shampoo for the treatment of scabies and lice. In addition to this PHA:

- The boxed warning emphasizes that it is a second-line treatment, updates information about its potential risks especially in children and adults weighing less than 110 pounds, and reminds practitioners that reapplication of Lindane Lotion or Lindane Shampoo is not the appropriate treatment, if itching continues after the single treatment.
- Lindane product package sizes will be limited to 1 and 2 ounces in order to minimize the potential for patients to apply the product in excess and to minimize reapplication of Lindane. Pharmacists should dispense a quantity sufficient for a single treatment, not to exceed 2 fluid ounces.
- A Medication Guide, designed to inform patients of the risks of Lindane products and provide instructions for appropriate use of the drugs, must now be dispensed by the pharmacist with each new prescription.

Lindane Products are Second-Line Treatments for Scabies and Lice

Lindane (gamma-hexachlorocyclohexane) is approved for topical treatment of pediculosis and scabies in patients "who have either failed to respond to adequate doses, or are intolerant of, other approved therapies." Lindane has been on the market since 1951, but was labeled as second-line therapy in 1995 because there are safer alternative treatments that should be used first. Second-line therapy is defined as:

1. The patient cannot tolerate the first-line drug of choice or
2. The patient has used the first-line drug of choice as instructed and the treatment has failed.

Examples of other medications approved to treat scabies and lice include the following:

Scabies:	permethrin cream 5% (Acticine, Elimite, Nix)
	crotamiton cream (Eurax)
Lice:	malathion lotion 0.5% (Ovide, prescription only)

	pyrethrum 0.33% with piperonyl butoxide shampoo and cream rinse
	permethrin cream rinse 1% (Nix and Rid)

Current Issues

FDA has determined that Lindane products have benefits that outweigh risks when used as directed. Most serious adverse events reported in association with Lindane products have been due to misuse. However, there have been rare case reports of serious reactions with apparently normal use. These reports highlight the need to emphasize the potential toxicity of Lindane in the product labels and educate healthcare providers and patients about the risks and how to minimize them, as well as to develop mechanisms to facilitate safe use, once the drug is dispensed to patients. These mechanisms include having Lindane products available only in small packaged amounts to avoid excess application and requiring that the Medication Guide be given to the patient by the pharmacist with each new prescription.

Current Safety Information

Safety information for Lindane comes from the FDA's Adverse Event Reporting System (AERS), which is derived from spontaneous adverse event reports through FDA's MedWatch Program and literature reports submitted to the Agency. Rates of adverse events cannot be calculated from this system and underreporting is presumed, especially for older products like Lindane Lotion and Shampoo.

The adverse events of concern for Lindane are systemic events due to absorption of this lipophilic drug following topical application. The majority of events occurred in patients with contraindications to the use of Lindane, in patients who used the medication in excessive amounts, or in those who misused the Lindane product. Of the adverse event cases in the FDA database with a serious outcome (hospitalization, disability or death), only 20% used Lindane according to the directions in the label. All other patients did not use Lindane according to directions in the label. Most commonly, patients often reapplied Lindane because of continued itching after the treatment, either on their own volition or at their doctor's recommendation.

Deaths

Three deaths due to Lindane use have been confirmed, although 17 deaths have been reported associated with Lindane use. The three confirmed deaths all included use of Lindane not in accordance with the label, including multiple topical applications or oral ingestion. Lindane toxicity was confirmed by autopsy in a child, and was diagnosed in an adult. The third death occurred in an adult who ingested Lindane for suicide purposes.

Of the remaining 14 deaths associated with Lindane, but not confirmed, there were 4 children, 9 adults and 1 patient of unknown age. All of these deaths occurred when Lindane was applied topically. In 9 cases, use was not in accordance with the label (exceeded label use - 7, oral administration – 1, use was contraindicated - 2). Scabies and head and/or pubic lice were the

predominant indications for use.

Neurologic Risks

The risk of neurologic side effects associated with Lindane is known from clinical trials, spontaneous post-marketing reporting data and literature reports. These side effects have ranged from dizziness to seizures. In post-marketing reports, neurologic side effects occurred in patients who misused Lindane, as well as in patients who used Lindane according to labeled instructions. Among the adverse event reports in the FDA database, 70% reported neurologic events including seizure, dizziness, headache and paresthesia.

Increased Risk in Younger and/or Smaller Patients and the Elderly

Lindane is contraindicated for use in neonates and should be used with extreme caution in children and in individuals weighing less than 50 kg (110 lbs). Among adverse event reports in which the outcome was serious (resulted in hospitalization, disability or death), the very young and the elderly appeared to be more susceptible to Lindane's adverse effects and had worse outcomes.

Animal studies have demonstrated that younger animals are more susceptible to the neurologic side effects seen with Lindane use. In addition, smaller children have a larger body surface to volume ratio that may result in proportionately larger risk of systemic exposure. For this reason, Lindane has long been contraindicated for use in neonates. It is not known whether the developing nervous system of children also increases their susceptibility to neurologic toxicity.

Other Populations with Increased Risk

Patients who have conditions, such as HIV infection, or take certain medications that may lower the seizure threshold should be prescribed Lindane with caution. They may be at greater risk for serious adverse events. The new Lindane label lists examples of some of these conditions and medications. The label also highlights special precautions for use of Lindane in women who are breastfeeding infants.

There are case reports of neurologic adverse events in nursing home patients treated with Lindane. Factors that may have increased their susceptibility to these adverse events include concomitant medications, underlying medical conditions, and advanced age. Special consideration should be given prior to treating this population with Lindane, even if they are greater than 50 kg.

Conclusion

Lindane products should be prescribed carefully, and quantities prescribed should be limited to amounts for a single application. Patients are at risk for serious neurologic adverse events, and even death, particularly with early retreatment. It is not known how soon after administering one dose of Lindane that a second dose can be safely administered. Post-treatment itching is common, especially in the treatment of scabies and does not

necessarily indicate treatment failure.

The instructions for Lindane use have been clarified in the products' professional labels and in the Medication Guides, which by law must be dispensed with all prescriptions of lindane. Because most of the serious adverse events reported have been because of misuse of Lindane Lotion and Lindane Shampoo, it is very important that patients understand the importance of using this medication in a manner consistent with product labeling.

The FDA wants healthcare providers to be aware of this new safety information and the changes that have occurred in the label for topical Lindane Lotion and Lindane Shampoo prescribed for the treatment of scabies and lice (both head and pubic lice), respectively. Healthcare providers should consider this new safety information when deciding whether to prescribe Lindane Lotion or Lindane Shampoo for patients who may be at risk for serious adverse drug sequelae.

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FDA/Center for Drug Evaluation and Research
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EXHIBIT 3

A Guide to Drug Safety Terms at FDA

Adverse drug reaction
An adverse drug reaction, also called a side effect, is any undesirable experience associated with the use of a medicine in a patient. Adverse events can range from mild to severe. Serious adverse events are those that can cause disability, are life-threatening, result in hospitalization or death, or are birth defects.

Boxed Warning
This type of warning is also commonly referred to as a "black box warning." It appears on a prescription drug's label and is designed to call attention to serious or life-threatening risks.

The Food and Drug Administration (FDA) approves a drug for marketing after determining that the drug's benefits of use outweigh the risks for the condition that the drug will treat. But even with a rigorous evaluation process, some safety problems surface only after a drug has been on the market and has been used in a broader population. This guide offers descriptions of some of the drug safety terms commonly used by FDA throughout the life cycle of a drug.

FDA REVIEW

Pre-Clinical Data
Before a drug can be tested in people in the United States, sponsors (drug manufacturers, research institutions, and other organizations that develop drugs) must show FDA results of testing they have done in laboratory animals and what they propose to do for human testing.

New Drug Approval Process
After the animal testing stage, FDA decides whether it is reasonably safe for the company to move forward with clinical trials—studies that evaluate the safety and effectiveness of a drug in healthy people and in patients. The drug company submits the results of such studies to FDA for review. The agency conducts a thorough review of the safety and effectiveness data, and considers how the benefits compare to the risks when making a decision of whether or not to approve a drug.

Adverse Drug Reaction
An adverse drug reaction, also called a side effect, is any undesirable experience associated with the use of a medicine in a patient. Adverse events can range from mild to severe. Serious adverse events are those that can

cause disability, are life-threatening, result in hospitalization or death, or are birth defects.

TAKING MEDICATION

Medication Guides

Medication Guides are paper handouts/pamphlets that are required to be distributed to patients with certain medications by the pharmacist. Medication Guides convey risk information that is specific to particular drugs and drug classes, and they contain FDA-approved information that can help patients avoid serious adverse events.
www.fda.gov/cder/Offices/ODS/medication_guides.htm

Consumer Medication Information (CMI)

Compared to a Medication Guide, a Consumer Medication Information sheet offers broader information on how to use a medicine. CMI sheets are not developed or regulated by FDA. These information sheets are prepared by pharmacies and given out with prescription drugs. CMI sheets are not available on the FDA Web site. The sheets help consumers understand key information about their prescription medicine, including how to take it, how to store it, and how to monitor their treatment. The sheets also include information on precautions and warnings, as well as symptoms of serious or frequent adverse events and what to do if you experience one.

Prescription Drug Labeling

Drug labeling, commonly called the package insert or the prescribing information, provides information to the physician about what a prescription medication is supposed to do, who should and should not take it, and how to use it. Labeling also includes information on a drug's side effects and warnings, and information from the clinical trials of the drug. Some prescription drug labeling also includes a part that describes the prescribing information in words that consumers will understand.

Nonprescription Drug Label ("Drug Facts")

For an over-the-counter (OTC), or nonprescription medicine, information printed on the medication bottle or package under the heading Drug Facts is important for taking care of yourself and your family. The Drug Facts tell you what a medicine is supposed to do, who should or should not take it, and how to use it. Safety information and instructions for use are displayed in a uniform and easy-to-read format.

Boxed Warning

This type of warning is also commonly referred to as a "black box warning." It appears on a prescription drug's label and is designed to call attention to serious or life-threatening risks.

MONITORING AFTER APPROVAL

Post-Market Surveillance

Post-market surveillance is the process by which a drug's safety is monitored on an ongoing basis after a drug is approved by FDA. Post-market surveillance seeks to identify problems that were not observed or recognized before approval and any problems that may arise because a drug may not be used as described in the drug labeling, or because a drug is being manufactured incorrectly.

Adverse Event Reporting System (AERS)

AERS is a computerized database containing reports of adverse events. It supports FDA's post-market safety surveillance program for all approved drugs and therapeutic biologics.
www.fda.gov/cder/aers/default.htm

MedWatch

MedWatch is FDA's safety information and adverse event reporting program. It provides important and timely medical product information to health care professionals, including information on prescription and over-the-counter drugs, biologics, medical devices, and special nutritional products. Health care professionals and consumers can also report serious problems they suspect are related to certain FDA-regulated products.
www.fda.gov/medwatch/safety.htm

REMOVAL FROM THE MARKET

Drug Recall

A drug recall is an action taken by a firm to remove a product from the market that FDA considers to be in violation of the law. Recalls are classified as Class I, Class II, or Class III. Class I recalls are the most serious and involve situations where there is a reasonable probability that the use of or exposure to a violative product, will cause serious adverse health consequences or death. A drug may be recalled due to factors such as problems with packaging, manufacturing, or contamination.

Drug Withdrawal

In rare cases, FDA may need to reassess and change its approval decision on a drug. A conclusion that a drug should no longer be marketed is based on the nature and frequency of the adverse events and how the drug's benefit and risk balance compares with treatment alternatives. When FDA believes that a drug's benefits no longer outweigh its risks, the agency will ask the manufacturer to withdraw the drug.

TYPES OF SAFETY ANNOUNCEMENTS

Early Communication About an Ongoing Safety Review

This type of communication is part of FDA's effort to communicate early with the public when the agency is still evaluating data and has not reached a conclusion. FDA shares information in the interest of informing doctors and patients about the issues that are under review and when FDA experts anticipate completing their review.

Public Health Advisories
These advisories provide important drug safety information and recommendations of actions that can be taken by patients or caregivers to avoid or minimize harm from a drug. They are issued when FDA has information that would help doctors and patients make better treatment choices.
www.fda.gov/cder/news/pubpress.htm

Letters to Health Care Professionals
These are letters—often referred to as "Dear Doctor" letters—that are developed by drug companies often with input from FDA. The letters educate health care professionals about new and important drug information.

Information for Health Care Professionals
Also referred to as a Healthcare Professional Information sheet, this information from FDA is for doctors, pharmacists, nurses, and other health care professionals. It contains an "alert" (a summary of the new safety information), detailed information about the safety issue, factors to consider when making treatment decisions, information for health care professionals to discuss with patients about their roles in reducing the risks from the drug, and a summary of the facts or data that serve as the basis for the information in the sheet.

FIND THE LATEST INFORMATION

Index to Drug-Specific Information
This index features an alphabetical listing of drugs that have been the subject of a Public Health Advisory, a Healthcare Professional Information sheet, an Early Communication About an Ongoing Safety Review, or other important information.
www.fda.gov/cder/drug/drugsafety/DrugIndex.htm

MedWatch Alerts
MedWatch provides important and timely medical product information, and is also a venue for reporting adverse events to FDA. You can sign up to receive MedWatch notices by e-mail. *www.fda.gov/medwatch/*

DailyMed
Developed with the National Library of Medicine, DailyMed is a Web site that gives physicians and patients electronic access to FDA-approved drug labels.
http://dailymed.nlm.nih.gov

Drugs@FDA
This resource allows you to search for information about FDA approved brand name and generic drugs and therapeutic biological products. These are proteins derived from living material (such as cells or tissues) used to treat or cure disease. You can search in many ways, including by drug name and active ingredient.
www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm

FDA Drug Safety Podcasts
Podcasting is a method of publishing and syndicating audio broadcasts through the Internet. These provide emerging safety information about drugs in conjunction with the release of Public Health Advisories.
www.fda.gov/cder/drug/podcast/default.htm

FDA Drug Safety Newsletter
Aimed at health care professionals, this quarterly publication is designed to enhance communication of safety information after a drug is marketed. The newsletter raises awareness of adverse events and stimulates reporting of adverse events.
www.fda.gov/cder/dsn/default.htm

FDA Consumer Health Information
FDA offers timely and easy-to-read articles on product approvals, safety warnings, and other health information. Articles cover all FDA-regulated products, including human drugs, drugs and feed for animals, medical devices, vaccines, blood, food, dietary supplements, and cosmetics. To find these articles, visit the Web page at *www.fda.gov/consumer/default.htm*

You can also sign up to receive notices of new consumer articles at *www.fda.gov/consumer/consumerenews.html*

Drug Product Recalls
FDA provides information on drug products that have been recalled due to manufacturing problems and/or safety concerns. In addition to information released to the public by a manufacturer using the normal media channels, FDA posts information about these recalled drug products at *www.fda.gov/opacom/7alerts.html*

You can also sign up to receive e-mail notices of product recalls.

Patient Safety News
This is a televised series for health care professionals, carried on satellite broadcast networks aimed at hospitals and other medical facilities across the country. It features safety information on new drugs, biologics, and medical devices.
www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/index.cfm

For More Information
FDA's Center for Drug Evaluation and Research
www.fda.gov/cder/index.html

FDA's Drug Safety Initiative
www.fda.gov/cder/drugSafety.htm

EXHIBIT 4

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

MORTON GROVE PHARMACEUTICALS, INC.,	)	
Plaintiff,	)	No. 08-CV-1384
vs.	)	Judge Bucklo Magistrate Judge Mason
THE NATIONAL PEDICULOSIS ASSOCIATION, INC.,	)	**JURY TRIAL DEMANDED**
Defendant.	)	

DEFENDANT THE NATIONAL PEDICULOSIS ASSOCIATION, INC.'S REVISED AFFIRMATIVE DEFENSES

Defendant, the National Pediculosis Association, Inc. ("NPA"), by and through its attorneys, Jenner & Block LLP, for its Amended Affirmative Defenses to Morton Grove Pharmaceuticals, Inc.'s ("Morton Grove") Complaint states as follows:

1. Morton Grove's claim under the Illinois Deceptive Trade Practices Act is barred by the applicable statute of limitations:

a. The statute of limitations applicable to Morton Grove's claim under the Illinois Deceptive Trade Practices Act is three years.

b. The statement, or a substantially similar statement, attributed to NPA and identified in Paragraph 23 of the Complaint was first published or disseminated more than three years before Morton Grove filed its complaint against NPA.

c. The statement, or a substantially similar statement, attributed to NPA and identified in Paragraph 26 of the Complaint was first published or disseminated more than three years before Morton Grove filed its complaint against NPA.

d. The statements, or substantially similar statements, attributed to NPA and identified in Paragraph 33 of the Complaint were first published or disseminated more than three years before Morton Grove filed its complaint against NPA.

e. The statement, or a substantially similar statement, attributed to NPA and identified in Paragraph 37 of the Complaint was first published or disseminated more than three years before Morton Grove filed its complaint against NPA.

f. The statement, or a substantially similar statement, attributed to NPA and identified in Paragraph 38 of the Complaint was first published or disseminated more than three years before Morton Grove filed its complaint against NPA.

g. The statement, or a substantially similar statement, attributed to NPA and identified in the first bulleted paragraph under Paragraph 40 of the Complaint was first published or disseminated more than three years before Morton Grove filed its complaint against NPA.

h. The statement, or a substantially similar statement, attributed to NPA and identified in the second bulleted paragraph under Paragraph 40 of the Complaint was first published or disseminated more than three years before Morton Grove filed its complaint against NPA.

i. The statement, or a substantially similar statement, attributed to NPA and identified in the fourth bulleted paragraph under Paragraph 40 of the Complaint was first published or disseminated more than three years before Morton Grove filed its complaint against NPA.

j. The statement, or a substantially similar statement, attributed to NPA and identified in the first bulleted paragraph under Paragraph 41 of the Complaint was first

published or disseminated more than three years before Morton Grove filed its complaint against NPA.

k. The statement, or a substantially similar statement, attributed to NPA and identified in the second bulleted paragraph under Paragraph 41 of the Complaint was first published or disseminated more than three years before Morton Grove filed its complaint against NPA.

2. Morton Grove's trade disparagement claim is barred by the applicable statute of limitations or the doctrine of laches:

a. The statute of limitations applicable to Morton Grove's trade disparagement claim is one year.

b. The statement, or a substantially similar statement, attributed to NPA and identified in Paragraph 23 of the Complaint was first published or disseminated more than one year before Morton Grove filed its complaint against NPA.

c. The statement, or a substantially similar statement, attributed to NPA and identified in Paragraph 25 of the Complaint was first published or disseminated more than one year before Morton Grove filed its complaint against NPA.

d. The statement, or a substantially similar statement, attributed to NPA and identified in Paragraph 26 of the Complaint was first published or disseminated more than one year before Morton Grove filed its complaint against NPA.

e. The statements, or substantially similar statements, attributed to NPA and identified in Paragraph 33 of the Complaint were first published or disseminated more than one year before Morton Grove filed its complaint against NPA.

f. The statement, or a substantially similar statement, attributed to NPA and identified in Paragraph 37 of the Complaint was first published or disseminated more than one year before Morton Grove filed its complaint against NPA.

g. The statement, or a substantially similar statement, attributed to NPA and identified in Paragraph 38 of the Complaint was first published or disseminated more than one year before Morton Grove filed its complaint against NPA.

h. The statement, or a substantially similar statement, attributed to NPA and identified in the first bulleted paragraph under Paragraph 40 of the Complaint was first published or disseminated more than one year before Morton Grove filed its complaint against NPA.

i. The statement, or a substantially similar statement, attributed to NPA and identified in the second bulleted paragraph under Paragraph 40 of the Complaint was first published or disseminated more than one year before Morton Grove filed its complaint against NPA.

j. The statement, or a substantially similar statement, attributed to NPA and identified in the third bulleted paragraph under Paragraph 40 of the Complaint was first published or disseminated more than one year before Morton Grove filed its complaint against NPA.

k. The statement, or a substantially similar statement, attributed to NPA and identified in the fourth bulleted paragraph under Paragraph 40 of the Complaint was first published or disseminated more than one year before Morton Grove filed its complaint against NPA.

l. The statement, or a substantially similar statement, attributed to NPA and identified in the first bulleted paragraph under Paragraph 41 of the Complaint was first published or disseminated more than one year before Morton Grove filed its complaint against NPA.

m. The statement, or a substantially similar statement, attributed to NPA and identified in the second bulleted paragraph under Paragraph 41 of the Complaint was first published or disseminated more than one year before Morton Grove filed its complaint against NPA.

n. To the extent no statute of limitations is applicable to Morton Grove's trade disparagement claim, a presumption of laches attaches after one year of delay.

o. Morton Grove demonstrated an unreasonable lack of diligence in failing to file suit earlier because, among other things: (1) NPA published or disseminated the statements or substantially similar statements through readily accessible public channels, such as the Internet; (2) as part of its mission to protect children from the misuse and abuse of potentially harmful lice and scabies treatments, NPA has long and publicly advocated its position that misuse and abuse of lice or scabies treatments containing the chemical lindane is the typical kind of use and that in light of the potential for misuse and abuse, the serious risks inherent even in use in accordance with FDA guidelines, and the potential for treatment failure caused by resistance, NPA generally discourages the use of treatments containing lindane; (3) Morton Grove was aware of its claims by November 30, 2007 at the latest, but it inexplicably delayed filing its complaint until March 7, 2008; and (4) Morton Grove had or should have had knowledge of NPA's statements or substantially similar statements long before it filed suit.

p. NPA has been prejudiced by Morton Grove's lack of diligence and unreasonable delay in filing suit because, among other things, during the period of Morton Grove's delay, NPA has spent time, effort, and financial resources developing its websites and otherwise advocating its position regarding lice or scabies treatments containing the chemical lindane.

q. For the reasons explained in paragraphs 2(b) through (p) of these Revised Affirmative Defenses, a presumption of laches applies to Morton Grove's trade disparagement claim, and Morton Grove has no excuse for its delay.

r. The public interest does not stand as a bar to the application of laches to Morton Grove's trade disparagement claim because, among other reasons, Morton Grove cannot show that the public has been harmed by the existence of NPA's statements.

3. Morton Grove's Lanham Act claim is barred by the doctrine of laches:

a. The statement, or a substantially similar statement, attributed to NPA and identified in Paragraph 23 of the Complaint was first published or disseminated more than three years before Morton Grove filed its complaint against NPA.

b. The statement, or a substantially similar statement, attributed to NPA and identified in Paragraph 26 of the Complaint was first published or disseminated more than three years before Morton Grove filed its complaint against NPA.

c. The statements, or substantially similar statements, attributed to NPA and identified in Paragraph 33 of the Complaint were first published or disseminated more than three years before Morton Grove filed its complaint against NPA.

d. The statement, or a substantially similar statement, attributed to NPA and identified in Paragraph 37 of the Complaint was first published or disseminated more than three years before Morton Grove filed its complaint against NPA.

e. The statement, or a substantially similar statement, attributed to NPA and identified in Paragraph 38 of the Complaint was first published or disseminated more than three years before Morton Grove filed its complaint against NPA.

f. The statement, or a substantially similar statement, attributed to NPA and identified in the first bulleted paragraph under Paragraph 40 of the Complaint was first published or disseminated more than three years before Morton Grove filed its complaint against NPA.

g. The statement, or a substantially similar statement, attributed to NPA and identified in the second bulleted paragraph under Paragraph 40 of the Complaint was first published or disseminated more than three years before Morton Grove filed its complaint against NPA.

h. The statement, or a substantially similar statement, attributed to NPA and identified in the fourth bulleted paragraph under Paragraph 40 of the Complaint was first published or disseminated more than three years before Morton Grove filed its complaint against NPA.

i. The statement, or a substantially similar statement, attributed to NPA and identified in the first bulleted paragraph under Paragraph 41 of the Complaint was first published or disseminated more than three years before Morton Grove filed its complaint against NPA.

j. The statement, or a substantially similar statement, attributed to NPA and identified in the second bulleted paragraph under Paragraph 41 of the Complaint was first published or disseminated more than three years before Morton Grove filed its complaint against NPA.

k. Morton Grove demonstrated an unreasonable lack of diligence in failing to file suit earlier because, among other things: (1) NPA published or disseminated the statements or substantially similar statements through readily accessible public channels, such as the Internet; (2) as part of its mission to protect children from the misuse and abuse of potentially harmful lice and scabies treatments, NPA has long and publicly advocated its position that misuse and abuse of lice or scabies treatments containing the chemical lindane is the typical kind of use and that in light of the potential for misuse and abuse, the serious risks inherent even in use in accordance with FDA guidelines, and the potential for treatment failure caused by resistance, NPA generally discourages the use of treatments containing lindane; (3) Morton Grove was aware of its claims by November 30, 2007 at the latest, but it inexplicably delayed filing its complaint until March 7, 2008; and (4) Morton Grove had or should have had knowledge of NPA's statements or substantially similar statements long before it filed suit.

l. NPA has been prejudiced by Morton Grove's lack of diligence and unreasonable delay in filing suit because, among other things, during the period of Morton Grove's delay, NPA has spent time, effort, and financial resources developing its websites and otherwise advocating its position regarding lice or scabies treatments containing the chemical lindane.

m. For the reasons explained in paragraphs 2(a) through (l) of these Revised Affirmative Defenses, a presumption of laches applies to Morton Grove's Lanham Act claim, and Morton Grove has no excuse for its delay.

n. The public interest does not stand as a bar to the application of laches to Morton Grove's Lanham Act claim because, among other reasons, Morton Grove cannot show that the public has been harmed by the existence of NPA's statements.

4. For the reasons explained in paragraphs 2(b) through 2(r) and 3(a) through 3(n) of these Revised Affirmative Defenses, the doctrine of laches precludes Morton Grove from obtaining injunctive or other equitable relief.

5. The doctrine of unclean hands precludes Morton Grove from obtaining injunctive or other equitable relief:

a. Morton Grove has actively engaged in an aggressive and targeted promotional campaign designed to mislead both consumers and health professionals about the dangers of its products, Lindane Shampoo and Lindane Lotion.

b. Through its false advertising or promotion of Lindane Shampoo and Lindane Lotion, Morton Grove intended to deceive the public regarding, among other things, the safety of Lindane Shampoo.

c. As part of this campaign, and as described more specifically in NPA's Counterclaim, Morton Grove has advertised and promoted its lindane pesticidal treatments in a manner that disregards, downplays, and discounts their serious risks and use restrictions, including those contained in the FDA's mandated "black box" public health warning for Lindane Shampoo and Lindane Lotion.

d. Morton Grove has engaged in its false advertising or promotion of Lindane Shampoo and Lindane Lotion in bad faith.

WHEREFORE, NPA respectfully requests that this Court enter judgment for NPA and against Morton Grove and grant NPA such other relief as this Court deems appropriate.

Dated: _____

Respectfully submitted,

THE NATIONAL PEDICULOSIS ASSOCIATION, INC.

By: _____
One of Its Attorneys

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